



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 516

[Docket No. FDA-2022-N-1128]

Defining Small Number of Animals for Minor Use Determination; Periodic Reassessment;

Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of December 14, 2022, for the final rule that appeared in the *Federal Register* of September 15, 2022. The direct final rule revises the “small number of animals” definition for dogs and cats in our existing regulation for new animal drugs for minor use or minor species. This document confirms the effective date of the direct final rule.

DATES: The effective date of December 14, 2022, for the direct final rule published September 15, 2022 (87 FR 56583) is confirmed.

FOR FURTHER INFORMATION CONTACT: Janah Maresca, Center for Veterinary Medicine (HVF-50), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-796-5079, email: janah.maresca@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of September 15, 2022 (87 FR 56583), FDA solicited comments concerning the direct final rule for a 60-day period ending November 14, 2022. FDA stated that the effective date of the direct final rule would be on December 14, 2022, 30 days after the end of the comment period, unless any significant adverse comment was submitted to FDA during the comment period. FDA did not receive any significant adverse comments.

Authority: 21 U.S.C. 360ccc-1, 360ccc-2, 371. Accordingly, the amendments issued thereby are effective.

Dated: December 9, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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